K101864

OCT 14 2010

Pre-Market Notification [510(k)] SUMMARY

Summary Date:	September 29, 2010
Trade Name:	KYPHON Xpander™ II Inflatable Bone Tamp
Common Name:	Inflatable Bone Tamp
Classification Names:	Arthroscope (21CFR888.1100)
	Orthopedic Manual Surgical Instrument (21CFR 888.4540)
Device Codes:	HRX, HXG
Regulatory Class:	Class II
Manufacturer's Name:	Medtronic Spine LLC
Manufacturer's Address:	1221 Crossman Avenue Sunnyvale, CA 94089 Establishment Registration No. 2953769
Contact Person:	Heinz J. Steneberg Senior Regulatory Affairs Program Manager Telephone: 408-548-6500 Fax: 408-548-6501
Performance Standards:	The requirements of the Food Drug and Cosmetic Act, under section 514 for performance standards, are not applicable to the KYPHON Xpander™ II Inflatable Bone Tamps.
Predicate Devices:	KyphX® Xpander Inflatable Bone Tamp (K041454)
Intended Use:	The KYPHON Xpander™ II Inflatable Bone Tamp is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a legally marketed PMMA-based bone cement that is cleared for use in kyphoplasty procedures) hand, tibia, radius and calcaneus.

Device Description: The KYPHON Xpander™ II Inflatable Bone Tamps are designed for reduction of fractures. The main components are the shaft, Y-Adapter and the inflatable balloon located at the distal tip.

Testing: The KYPHON Xpander™ II Inflatable Bone Tamps met the specifications and performance characteristics and are substantially equivalent to the predicate devices. The testing included functional testing, such as balloon compliance, deflation time, insertion/withdrawal force and fatigue testing as well as mechanical testing, such as tensile strength and torsional strength testing.

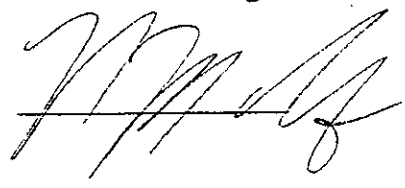
Biocompatibility: Biocompatibility testing of the KYPHON Xpander™ II Inflatable Bone Tamps confirmed that the devices meet applicable requirements of the FDA Blue Book Memorandum #G95-1 entitled "Use of International Standard ISO-10993, "*Biological Evaluation of Medical Devices Part-1: Evaluation and Testing*" and are biocompatible.

Sterilization: The KYPHON Xpander™ II Inflatable Bone Tamps will be provided sterile, for single-use only.

Packaging and Labeling: The KYPHON Xpander™ II Inflatable Bone Tamps are packaged in a pouch made from polyamide, ultra-low density polyethylene and 1073B Tyvek® and a carton.

Substantial Equivalence: The information submitted in this premarket notification supports a determination that the KYPHON Xpander™ II Inflatable Bone Tamp is substantially equivalent in technological characteristics and intended use to the predicate devices. The products have the same fundamental scientific technology, basic design, functional characteristics and the same clinical application.

Submitted by: Heinz J. Steneberg



Date Submitted: September 29, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Spine LLC
% Mr. Heinz J. Steneberg
Senior Regulatory Affairs Program Manager
1221 Crossman Avenue
Sunnyvale, California 94089

OCT 14 2010

Re: K101864
Trade/Device Name: KYPHON Xpander™ II Inflatable Bone Tamp
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HXG
Dated: September 08, 2010
Received: September 09, 2010

Dear Mr. Steneberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101864
OCT 14 2010

INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: KYPHON Xpander™ II Inflatable Bone Tamp

Indications for Use:

The KYPHON Xpander™ II Inflatable Bone Tamp is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures) hand, tibia, radius and calcaneus.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101864